JUN 3 0 2014

510(k) SUMMARY

Date	June 27, 2014
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Trade Name	SpineVision LUMIS™ Cannulated Pedicle Screw Fixation System SpineVision U.L.I.S.™ Pedicle Screw Fixation System
Common Name Classification Name	Pedicle Screw Spinal System
Product code	MNI, MNH, KWQ, KWP
CFR section	888.3070, 888.3050
Legally marketed predicate devices	LUMIS™ Pedicle Screw Fixation System (K112607/K130302) U.L.I.S.™ Pedicle Screw Fixation System (K112607/K130302) UNI-THREAD Spinal System(K013301) Scient'x Polyaxial LP (K062912) Xia Spinal System (K050461/K052761/K060361/K060748/ K071373/K113666) VIPER® System, VIPER®2 system (K061520/K111571/ K090648/K102701) EXPEDIUM® Spine System (K041119/K062174/K090230/ K090799) DePuy Spine - Moss Miami-titanium (K955348) Alphatec Zodiac (K071890)

Description	The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are composed of cannulated (LUMIS™) and non-cannulated (U.L.I.S.™) pedicle screws and fixation rods Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient and are supplied non-sterile. The purpose of this submission is to include design modification and new diameters and lengths of the LUMIS™ Cannulated Polyaxial Pedicle Screws and U.L.I.S.™ Polyaxial Pedicle Screws, creation of LUMIS™ Cannulated Monobloc Pedicle Screws and U.L.I.S.™ Monobloc Pedicle Screws, addition of CoCr Spinal Rods, and new lengths of UNI-Thread® rods.
Material	Titanium Ti-6Al-4V ELI per ASTM F136 (ISO 5832-3) Cobalt Chromium (CoCr) alloy per ASTM F1537
Intended use	When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for: • Degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) • Spondylolisthesis • Fracture • Spinal stenosis • Curvatures (i.e. scoliosis, kyphosis, and/or lordosis) • Tumors • Failed previous fusion (pseudoarthrosis) The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who: • have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra; • receive fusions using autogenous bone graft only; • have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and • have the device removed after the development of a solid fusion. In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to

	fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1): • Degenerative spondylolisthesis with objective evidence of neurologic impairment • Fracture • Curvatures (i.e. scoliosis, kyphosis, and/or lordosis) • Spinal tumor • Failed previous fusion (pseudoarthrosis)
Summary of Technological Characteristics	The SpineVision Universal Lumbar Intuitive System (U.L.I.S.™System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are manufactured in Titanium Ti-6Al-4V ELI complying with ASTM F136 and CoCr complying with ASTM F1537. The LUMIS™ Pedicle screw system is cannulated. The devices provide correction and rigid stabilization of the spine during development of solid bone fusion following corrective spine surgery for a number of indications (listed above).
Performance data	The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) conform to special control established for Pedicle Screw Spinal System and to "Spinal System 510(k)s – Guidance for Industry and FDA Staff Document" issued on May 3, 2004. Mechanical testing was conducted per ASTM F1717-13 "Standard Test Methods for Spinal Implant Constructs in Vertebrectomy Model" and ASTM F1798-13 "Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants. Testing according to ASTM F1717-13 includes Static Compression, Static Torsion and Dynamic Compression. ASTM F1798-13 testing was Transverse Test Apparatus for Subassembly. Results demonstrate comparable mechanical properties to the predicate devices. No clinical data has been presented.
Substantial equivalence	SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are substantially equivalent to their predicate devices in terms of intended use, material, design, mechanical properties and function.

Conclusion	Engineering analysis and design validation/verification were used to support substantial equivalence. SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

SpineVision, S.A.
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K133575
Trade/Device Name: SpineVision U.L.I.S.™ Pedicle Screw Fixation System and LUMIS™ Cannulated Pedicle Screw Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP, KWQ
Dated: June 10, 2014
Received: June 13, 2014

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133575

Device Name
SpineVision U.L.I.S.™ Pedicle Screw Fixation System and LUMIS™ Cannulated Pedicle Screw Fixation System

Indications for Use *(Describe)*
When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):

- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- spinal tumor
- failed previous fusion (pseudoarthrosis)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Zane W. Wyatt
Division of Orthopedic Devices

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